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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/970,458	10/02/2001	Jan Seppala	S63.2-10087	9618

490 7590 09/14/2004

VIDAS, ARRETT & STEINKRAUS, P.A.  
6109 BLUE CIRCLE DRIVE  
SUITE 2000  
MINNETONKA, MN 55343-9185

EXAMINER

BAXTER, JESSICA R

ART UNIT	PAPER NUMBER
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3731

DATE MAILED: 09/14/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

09/970,458

**Applicant(s)**SEPPALA ET AL. *CIN***Examiner**

Jessica R Baxter

**Art Unit**

3731

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 20 May 2004 and 15 July 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-7 and 10-18 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-7 and 10-18 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on May 20, 2004 has been entered.

### ***Claim Rejections - 35 USC § 103***

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claim 1-3, 5, 7, 10-14, 16 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,944,726 to Blaeser et al. in view of U.S. Patent No. 5,445,646 to Euteneuer et al.

Blaeser discloses a stent delivery system comprising a stent delivery catheter (10), the stent delivery catheter having a stent mounting region, the stent mounting region having an inflatable portion (14); a stent (18) disposed about the stent mounting region, the stent having an unexpanded position and an expanded position; a first and second stent retaining sleeve (36,38) having first and second ends, the first end being attached to the stent delivery

Art Unit: 3731

catheter (Column 3 lines 60-67), the first and second stent retaining sleeve disposed about at least a portion of the stent in the unexpanded position (FIGS. 3-7), the first and second stent retaining sleeves being constructed and arranged to retract toward the attached first end when the stent is expanded (FIGS. 3-5), thereby shortening the distance between the first and second ends of the first and second stent retaining sleeves. Blaeser discloses the claimed invention except for the first and second stent retaining sleeves covering substantially the entire stent in the unexpanded position. Euteneuer teaches that the proximal and distal retaining sleeves overlap to form a seal and protect the stent from bodily fluids during delivery (Column 3 lines 17-22, Column 6 lines 44-48). It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the device of Blaeser with the overlapping stent retaining sleeves in order to provide a seal between the sleeves to protect the stent from being exposed to bodily fluids while it is being delivered.

3. Claims 4 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Blaeser et al. '726 in view of Euteneuer et al. '646, as applied above, further in view of U.S. Patent No. 6,168,617 to Blaeser et al.

Blaeser '726, as modified, discloses the claimed invention except for the first and second stent retaining sleeves having a plurality of openings. Blaeser teaches that the stent retaining sleeves may be provided with a plurality of holes to enhance their flexibility (Column 6 lines 9-13). It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the device of Blaeser '726, as modified, with a plurality of openings in order to increase the flexibility of the device.

Art Unit: 3731

4. Claims 6 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Blaeser et al. '726 in view of Euteneuer et al. '646, as applied above, and further in view of U.S. Patent No. 5,919,170 to Woessner.

Blaeser, as modified, discloses the claimed invention except for the stent retaining sleeves being made of alternating strips of two materials. Woessner teaches that alternating strips of material are provided in a catheter in order to provide visual monitoring of the device (Column 2 lines 33-46). It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the device of Blaeser, as modified, with the alternating stripes of material in order to monitor the device as it travels through vessels in the body.

### ***Response to Arguments***

5. Applicant's arguments filed May 20, 2004 have been fully considered but they are not persuasive.

6. In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, Euteneuer et al. '646. teaches that the sleeves overlap to form a seal around the stent in order to protect the stent from body fluids during delivery (Column 3 lines 13-22). The seal that forms around the stent is formed by two overlapping sleeves, which substantially cover the entire stent during delivery.

Art Unit: 3731

7. Applicant argues that the waterproof chamber requires additional elements. Applicant points to Column 6 lines 39-50 to support their position. This paragraph, teaches that two sleeves overlap to form a seal. There is no indication that additional elements are needed to form the chamber around the stent. The additional elements in that section (bands 18) are used to hold a self-expanding stent in place during delivery.

### *Conclusion*

8. All claims are drawn to the same invention claimed in the application prior to the entry of the submission under 37 CFR 1.114 and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the application prior to entry under 37 CFR 1.114. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action after the filing of a request for continued examination and the submission under 37 CFR 1.114. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Art Unit: 3731


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jessica R Baxter whose telephone number is 703-305-4069. The examiner can normally be reached on M-F 8:30AM - 5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan T Nguyen can be reached on 703-308-2154. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
jrb

Jessica R Baxter  
Examiner  
Art Unit 3731

  
**DAVID O. REIP**  
**PRIMARY EXAMINER**